REMARKS

THE PRESENT AMENDMENT

Claim 14 is now amended to correct the claim dependency. Claim 14 should depend upon claim 3 rather than claim 1.

Claim 61 is now amended to correct the antecedent basis for the claim to refer to the "agent" of claim 57. The support for adding the additional agents at the end of claim 61 may be found in the specification within the listing of agents in paragraph 0069 and in claim 62 as filed.

Claim 62 is now amended to reword the claim in proper format and correct the spelling of several of the agents listed. Support for adding the specific composition of radioactive particles at the end of the claim may be found in the specification within the listing of agents in paragraph 0069 and in Provisional Patent Application 60/437,541 (incorporated by reference into the present application). The terms .alpha. and .beta. at bottom line of page 5 are replaced by the corresponding Greek letters.

RESTRICTION/ELECTION OF SPECIES REQUIREMENT

In the action mailed October 5, 2007 (being paper no 20070927), the Examiner required restriction of the application to one of eleven groups of claims, described by the Examiner as follows:

> Group I, claim(s) 1-14, drawn to a method for delivering a substance transdermally by providing a substance within microcapsules onto a patch on the skin, then applying energy to the patch to release the substance.
>
> Group II, claim(s) 15-31, drawn to a patch comprising an inner and outer disc.
>
> Group III, claim(s) 32-47, drawn to a composition comprising a substance within microcapsules that are ruptured by a change in chemical potential.
>
> Group IV, claim(s) 48, drawn to a composition comprising agents encapsulated in microspheres and a pressure-sensitive adhesive.

Group V, claim(s) 49, drawn to a composition comprising agents encapsulated in microspheres and hydrogel.

Group VI, claim(s) 50, drawn to a composition comprising agents encapsulated in microspheres and a hydrocolloid.

Group VII, claim(s) 51, drawn to a composition comprising agents encapsulated in microspheres and a medium in a patch.

Group VIII, claim(s) 52, 53, and 57-62, drawn to a method for delivering an encapsulated agent by applying ultrasound.

Group IX, claim(s) 54 and 57-62, drawn to a method for delivering an encapsulated agent by applying heat.

Group X, claim(s) 55, drawn to a device comprising ultrasound sources.

Group XI, claim(s) 56, drawn to a device comprising heating sources.

Claims 57-62 are linking claims and, if Group VIII or IX is elected, will be examined to the extent they read on the elected Group.

In the action mailed October 5, 2007, (being paper no. 20070927), the Examiner also required election of a single species for examination. The species are as described by the Examiner as follows:

Substances in Groups I-III: (a) drug, (b) biologically active compound, (c) excipient, (d) skin permeation enhancer, (e) insulin, and (f) vitamin, as in claims 9-12, 27-30, and 43-46.

Active agents in Groups VIII and IX: numerous, as in claims 58-62.

Applicant hereby provisionally elects **Group I** (being claims 1-14). Applicant amends claim 14 to correct dependency. Applicant partially traverses this election requirement, as explained below. The claims of Groups VIII and IX, namely claims 52-54 and 57-62, are provisionally withdrawn without prejudice subject to the traversal explained below. Applicant cancels without prejudice the claims to Groups II -- VII, X, and XI, namely claims 15-51, 55-56. Applicant reserves the right to prosecute the cancelled and withdrawn claims in future divisional patent applications.

Applicant provisionally elects **Species (b)** (biologically active compound) while nevertheless traversing the requirement for election of species, as explained below.

PROTEST TO HOLDING OF LACK OF UNITY AND SPECIES ELECTION

Applicant respectfully traverses Examiner's holding that Groups I, VII, IX recite inventions that aren't within a single general inventive concept, under PCT Rule 13.1. The claims of these groups, claims 1-14, 52-54, and 57-62, are directed toward methods for the delivery of an active substance through a dermal layer. As such these claims should be examined together as a single general inventive concept.

Under PCT Rule 13.3 a determination of whether a group of inventions are so linked as to form a single general inventive concept is made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Claims 1-14 recite a general three-step method for delivering an encapsulated substance through at least one dermal layer. Claims 52-54 and claims 57-62 recite specific embodiments of the method directed at delivering specific types of encapsulated substances (or sometimes, agents) through a dermal layer using ultrasound or heat to rupture the microcapsules. All of these claims are method claims that further define embodiments of the method of the invention. As method claims they should be examined together as a single inventive unit. According to PCT Rule 13.3 there should be no determination that they are separate inventive concepts because the inventions appear in separate claims. Nor should they be considered separate inventions because the concept of the method is expressed differently in the claims. For these reasons, Applicant believes Examiner should review claims 1-14, 52-54, and 57-62 as a single inventive unit.

Should Examiner fail to be persuaded to examine these claims as a single

inventive unit, then Applicant reserves the right to prosecute the withdrawn claims 52-54, and 57-62 in future divisional patent applications.

Applicant cancels the claims of Groups II – VII, X, XI., without prejudice, thereby reserving the right to prosecute the cancelled claims in future divisional patent applications

Applicant hereby partially traverses Examiner's determination of species for an election of species requirement.

Applicant is not seeking to claim the compounds and compositions that are described within the specification and recited in the claims. An important aspect of the invention is the ability to deliver the active substance through at least one layer of the skin The compounds are examples of substances or agents useful in performance of the claimed methods. No one specific substance or agent of the Examiner's list of "species" is critical for the operation of the invention. The term "active substance" is intended to mean any substance for which transdermal or subdermal delivery is to be accomplished [¶ 0003 of specification].

The Examiner has designated the species of this invention to include (a) drug, (b) biologically active compound, (c) excipient, (d) skin permeation enhancer, (e) insulin, (f) vitamin, and numerous active agents found in claims 58-62.

Applicant submits that species (b) "biologically active compound" is a generic term that embraces drugs, insulin, and vitamins. Drugs, insulin, and vitamins are each substances that have biological effects on the body. Each has some level of biological activity and therefore is a biologically active compound. Each term is embraced by the term "biologically active compound" and may be considered as a subset of the broader term "biologically active compound". Therefore there is no reasonable distinction between the "species", biologically active compound, drug, insulin, and vitamin. Therefore applicant respectfully request that the Examiner

withdraw the species election requirement with respect to the "species" (a), (b), (e), and (f), all of which are within the scope of biologically active compounds.

CONCLUSION

This is intended to be a complete response to the outstanding Examiner's Action. If the Examiner has any questions, she is invited to phone Applicant's attorney at the phone number given below

Respectfully submitted:

December 5, 2007

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